REMARKS

Claims Rejection - 35 U.S.C. §103

Claims 1-8, 10, 11, 13-15, 17, and 19-22 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 4,737,140 to Lee (the "Lee Patent").

Claim 1

The Examiner concedes that, with respect to independent Claim 1, the Lee Patent does not explicitly teach an ivac bottle for drawing and transporting fluid through the cuvette. However, the Examiner argues that the Lee Patent teaches a peristaltic pump 12 and therefore this pump is considered an equivalent of the pump in accordance with 35 U.S.C., sixth paragraph.

Applicant respectfully disagrees. *First,* the claim limitation of an "ivac bottle for drawing and transporting fluid through the cuvette" does not invoke 35 U.S.C. 112, sixth paragraph and, therefore, the use of this provision by the Examiner is inapplicable here.

Second, the teaching of the Lee Patent teaches away from using an ivac bottle for drawing and transporting fluid through the cuvette. The Lee Patent discloses that, using a pump, the patient blood is infused with an anticoagulant agent, then, using a clamping means and blood pump, the blood is moved or flows into a centrifuge bowl. The centrifuge bowl then continually rotates until such time as the red blood cells are separated from the white blood cells. Once the centrifuge is no longer capable of further separating the red blood cells from the white blood cells, an operator, using a control panel, directs the centrifuge to be emptied. The red blood cells are then pumped into return container 21 and never treated with radiation. The separated white blood cells are then pumped into container 22, delivered through line 501 to an inlet 209, through a serpentine pathway for irradiation in the irradiation chamber, and exited outlet 210 into line 511 (which monitors fluid temperature). A roller pump mechanism then moves the blood from line 511 through line 508 to outlet tube 511 and toward outlet 502 for returning back to container 22.

Thus, in the Lee Patent, in order to draw and transport the blood through the serpentine pathway of the apparatus requires a pump, a clamping means, a blood pump, a centrifuge bowl, an operator to direct a control panel, a container, and a roller pump mechanism. Without any one of these, the Lee Patent would presumably not work as disclosed. Furthermore, the blood that is drawn from the patient is transported to and through the apparatus and serpentine pathway in several different stages and varying rates. For example, the centrifuge bowl requires time to process and separate the blood which will be different for each patient due to the differing densities of the individual's blood components. This is the reason that an operator must then be continually watching the centrifuge bowl to make a determination of when the centrifuge bowl can no longer separate the blood so that the operator can manually use the control panel to empty the centrifuge bowl into the container. These determinations by the operator vary depending upon the blood and the person who is acting as the operator.

On the contrary, the use of the ivac bottle by the Applicant draws and transports the fluid through the cuvette in a simple, direct, and constant controlled rate which is completely different than in the Lee Patent. As a result, Applicant's device treats all of the blood (i.e., both the red and white blood cells combined) and not just the white blood cells as in the Lee Patent. This enables Applicant to treat a much larger spectrum of viruses and creates a simple, more effective device than the apparatus in the Lee Patent. Thus, given the disclosures in the Lee Patent and the differences with Applicant's device, the Lee Patent teaches away from Applicant's device and the use of an ivac bottle.

Lastly, Applicant submits that the use of an ivac bottle in the apparatus of the Lee Patent would result in an inoperable structure. Given the disclosures in the Lee Patent requiring a pump, a clamping means, a blood pump, a centrifuge bowl, an operator to direct a control panel, a container, and a roller pump mechanism along with the different stages and varying rates employed to draw and transport the blood through the apparatus, replacing all of these with an ivac bottle like in Applicant's device would clearly not work in the Lee Patent rendering the apparatus inoperable.

Based on the foregoing, Applicant submits that the Lee Patent as suggested by the Examiner would not be an equivalent of or obvious to one of ordinary skill in the art to modify to create the combination of elements found in Claim 1. Accordingly, Applicant submits that independent Claim 1, as previously amended, presents allowable subject matter.

Claims 2-7 and 10-12

As Claims 2-7 and 10-12 depend from independent Claim 1 which, as previously amended, presents allowable subject matter, Claims 2-7 and 10-12 likewise present allowable subject matter.

Claim 13

With respect to independent Claim 13, the Examiner argues that Applicant's claim limitation of "means for returning the fluid back through the same cuvette from the means for receiving the fluid" is obvious "since Lee teaches either the specific elements or equivalents thereof in accordance with 35 U.S.C. 112, sixth paragraph, [and] Lee teaches a means for returning fluid back through the cuvette."

For further distinction, Applicant has amended the limitation of Claim 13 to "means for returning the fluid in the opposite direction back through the cuvette from the means for receiving the fluid." As amended, Applicant respectfully disagrees with the Examiner. *First*, the teaching of the Lee Patent teaches away from Applicant's invention and returning the fluid in the opposite direction back through the same cuvette to irradiate the blood in at least two separate instances. The Lee Patent discloses that:

> "Referring now to FIG. 2, the ... blood ... is delivered through line 501 to the inlet 209 of the flat plate irradiator 513. ... The fluid flows upward through the serpentine pathway in cavity 503 in the irradiation chamber to outlet 210. ... Outlet tubing 511 passes through the pump block 504 ..., affixed to the end of the flat plate irradiator 513, and then connects to return line 35 which returns fluids from the irradiation chamber to container 22." [Col. 6, Lines 11-

32].

"Continued operation of the recirculation pump rotor 203 *continuously* recirculates the leukocyte enriched fluid from container 22 through the chamber for receiving photoactivating radiation from the energized light array assembly 401 (FIG. 3) and back to container 22." [Col. 6, Lines 54-59 (*emphasis added*)]. "Thereafter container 22 is ideally removed to stand 15 ... for reinfustion of the treated blood portion into the patient." [Col. 7, Lines 34-38].

Since the blood that is radiated in the Lee Patent (i) flows in only one direction from the container 22, (ii) through the irradiation chamber 513 only one time, (iii) returns directly to the container 22, and (iv) is specifically directed to be reinfusioned from the container 22 back into the patient, the Lee Patent expressly teaches away from Applicant's invention and returning the fluid in the opposite direction back through the same cuvette to irradiate the blood in at least two separate instances.

Second, Applicant disagrees with the Examiner that Lee teaches a means for returning the fluid back through the cuvette to irradiate the blood a second time using the same cuvette as claimed and amended.

As disclosed in the Lee Patent, during a treatment, the blood must pass through line 501 to enter inlet 209 of the flat plate irradiator 513, flow through the serpentine pathway in cavity 503, and then exit outlet 210, returning to container 22 through outlet tubing 511 and 501 and return line 35. [Col 6, Lines 11-32]. Of particular importance is that there is no disclosure in the Lee Patent to collect all the blood after it exits outlet 210 having just been treated in the serpentine pathway, then return this exact same blood in *the opposite direction* back through the exit outlet 210, back through the serpentine pathway in cavity 503, and then exiting in *the opposite direction* out the inlet 209 and line 501 for returning to container 22. Furthermore, it would not be obvious to one skilled in the art to attempt to return the blood in the opposite direction as the Lee Patent discloses that the blood is *continuously* circulated through the irradiation chamber and back to the container 22. [Col. 6, Lines 54-59].

Lastly, Applicant asserts that the Examiner's position is provided in light of Applicant's disclosure and that the Examiner is relying upon hindsight in proposing that the apparatus in the Lee Patent can be modified to provide the means for returning the fluid in the opposite direction back through the same cuvette from the means for receiving the fluid. With knowledge of Applicant's device, Applicant's invention appears obvious to the Examiner. However, but for the Examiner's knowledge of Applicant's device, the modification of the apparatus in the Lee Patent would not have occurred to the Examiner. Applicant's assertion is further supported by the fact that those skilled in the art have not designed Applicant's device. Thus, the Lee Patent cited by the Examiner is predicated upon the Examiner's knowledge of Applicant's device and is not obvious to a person of ordinary skill in the art.

Based on the foregoing, Applicant submits that the Lee Patent as suggested by the Examiner would not be an equivalent of or obvious to one of ordinary skill in the art to modify to create the

combination of elements found in Claim 13, as amended. Accordingly, Applicant submits that independent Claim 13, as amended, presents allowable subject matter.

Claims 14-17 and 19

As Claims 14-17 and 19 depend from independent Claim 13, which as amended, presents allowable subject matter, Claims 14-17, and 19 likewise presents allowable subject matter.

Claim 20

With respect to independent Claim 20, the Examiner appears to argue that the Lee Patent teaches the limitations of (f) through (j) and that the "irradiated blood portion from container 22 [can be] returned to the patient via a centrifuge 13 until the desired amount of leukocyte enriched blood is achieved."

Applicant respectfully disagrees. *First*, just as the Lee Patent does not disclose and it would not be obvious to one skilled in the art to modify the apparatus to provide "a means for returning the fluid back through the cuvette to irradiate the blood a second time using the same cuvette" as discussed *infra* with respect to Claim 13, the same arguments presented would apply to and render as non obvious "transporting the irradiated fluid back through the same conduit and back into the same cuvette" as claimed in limitation (g) of Claim 20.

Second, the argument presented by the Examiner appears to constitute an inoperable structure. For example, in limitation (i), Claim 20 claims "transporting the second irradiated fluid back through the *same conduit* from the cuvette." (*Emphasis added*). In order for the Lee Patent to transport the fluid back through the same conduit from the serpentine pathway, as suggested by the Examiner, the blood must be pumped from container 22 back through the line and valve 16c and back into the centrifuge 13. As the centrifuge 13 is disclosed in the Lee Patent to continuously separate the blood received from the patient into the centrifuge through line 24, this would clearly create problems in the apparatus. The blood coming from the patient is the full blood (i.e., it contains both red blood cells and white blood cells). This blood is not separated and untreated. The blood from container 22, on the other hand, contains only white blood cells, is treated, and been prevously mixed with a predetermined volume of plasma. Thus, mixing the full untreated blood coming into the centrifuge from the patient at one end with the treated white blood cell blood with plasma coming into the centrifuge from the other end would render the apparatus completely ineffective and arguably inoperable.

Based on the foregoing, Applicant submits that the Lee Patent as suggested by the Examiner does not disclose and would not be obvious to one of ordinary skill in the art to modify to create the combination of elements found in Claim 20, as previously amended. Accordingly, Applicant submits that independent Claim 20, as previously amended, presents allowable subject matter.

Claim 21

As Claim 21 depends from independent Claim 20, which, presents allowable subject matter, Claim 21 likewise presents allowable subject matter.

Claim 22

The Examiner concedes that, with respect to independent Claim 22, the Lee Patent does not explicitly teach the step of "reversing the directional flow of the fluid to pass back through the same cuvette." However, the Examiner argues that Lee teaches several cycles or pass throughs and that therefore it would be obvious to modify Lee to accomplish this step.

Applying the same arguments presented *infra*, Applicant respectfully submits that the Lee Patent as suggested by the Examiner does not disclose and would not be obvious to one of ordinary skill in the art to modify to reverse the directional flow of the fluid to pass back through the same cuvette as claimed in Claim 22. Accordingly, Applicant submits that independent Claim 22 presents allowable subject matter.

Applicant submits that the application is now in condition for allowance and respectfully requests the Examiner to take such action.

If the Examiner believes that a telephone interview with Applicant's attorney would be beneficial, please do not hesitate to contact the undersigned.

Respectfully submitted,

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